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EXAMINER	
RIGGS II, LARRY D	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/632,099	CHEN ET AL.	
	Examiner	Art Unit	
	LARRY D. RIGGS II	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,13,14 and 58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,13,14 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07 December 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed 19 May 2008 are acknowledged and entered.

Status of Claims

Cancellation of claims 6, 10-12, 15-56 and 58-61 are acknowledged. Claims 1-5, 7-9, 13, 14 and 57 are currently pending and under consideration.

Withdrawn Rejections/Objections

The objection of the disclosure in the Office action mailed 19 November 2007 is withdrawn in view of the amendments filed 19 May 2008.

The objection to claims 6 and 25, in the Office action mailed 19 November 2007 is withdrawn in view of the amendments filed 19 May 2008.

The rejection of claims 1-31 and 57 under 35 U.S.C. 112, Second Paragraph in the Office action mailed 19 November 2007 is withdrawn in view of the amendment filed 19 May 2008.

The rejection of claims 1-15, 18-27, 29-31 and 57 under 35 U.S.C. 102(b) in the Office action mailed 19 November 2007 is withdrawn in view of the amendment filed 19 May 2008.

The rejection of claims 16, 17 and 28 under 35 U.S.C. 103(a) in the Office action mailed 19 November 2007 is withdrawn in view of the amendment filed 19 May 2008.

Oath/Declaration

Applicants have attempted to contact inventor Keith Steward to execute a new declaration without success.

This objection is reiterated from the Office action mailed 19 November 2007.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). In the instant case, the post office address of inventor Keith Steward was changed, but the alternation was not initialed and dated. See page 10, 15, 19 of the amended oath filed 09 January 2007.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

It is noted by applicant's remarks, filed 19 May 2008, that this application appears to claim subject matter disclosed in prior provisional Application No. 60/353176, filed 04 February 2002. However, a reference to this provisional application is not present in the first paragraph of the specification or in the Application Data Sheet

of the instant application. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference

required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 7-9, 13, 14 and 5 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant invention is drawn to a method for identifying a drug discovery target which comprises providing a means for accessing genomics information in a database wherein said means permits computational analysis of biological relationships among the stored concepts, generating one or more subsets of genomics information from the database wherein at least one of the one or more subsets is a disease-related pathway, and identifying the biological interactions and actor concepts in the disease-related pathway whereby each of the actor concepts involved in each such reaction is a drug discovery target.

Since the claimed invention involves mathematical algorithm, which is a judicial exception, the following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm).

The Guidelines states:

> *To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways (Guidelines, p. 19):*
>
> *- The claimed invention "transforms" an article or physical object to a different state or thing.*
> *- The claimed invention otherwise produces a useful, concrete and tangible result.*

In the instant claims, there is no physical transformation by the claimed invention because a computer for storing and accessing genomics information, querying a

database, identifying biological objects and process and accessing drug discovery targets are not physical transformations. Thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result.

In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful", the claim must produce a final result that is specific, substantial and credible. For a claim to be "tangible", the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete", the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Method claims 1-5, 7-9, 13, 14 and 5 do not produce a tangible final result. A tangible requirement requires that the claim must set forth a practical application of accessing the drug discovery targets, to produce a real-world result. The instant claims are drawn to a method of identifying drug discovery targets. However, the last step of the claims includes identifying biological objects and processes that act on those objects, wherein those objects and process are drug targets, the result of the invention is a set of data, such as identified objects and processes, i.e. drug targets, which, in itself, is not tangible. Since the claim itself must include a useful, concrete and tangible final result, the instant claims are non-statutory.

This rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

Response to Arguments

Applicant's arguments filed 19 May 2008 have been fully considered but they are not persuasive.

Applicants argue use of computer generated data necessarily requires the accessing or outputting of results.

Applicant's arguments are not persuasive. The instant invention is a method. Providing a computer for storing and accessing information is only part of the method. The final step of the invention is identifying and then accessing drug discovery targets, but there is no tangible result to the user. Accessing drug targets is not a result provided to a user.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 7-9, 13, 14 and 57 are rejected under 35 U.S.C. 102(a) as being anticipated by Qu et al.

The instant claims are drawn to a method of identifying drug discovery targets.

Regarding claim 1, Qu et al. teaches a bioinformatics system that performs multidimensional data analysis to discover gene functions and uses cluster analysis to infer gene relationships to discover drug targets. Qu et al. shows accessing genomics information through data warehousing, (see page 21, right column; page 22, left and middle columns), generating subsets of information that are disease-related pathways through data integration, (see page 22, middle and right columns; pages 25-26, Figure 4) and identifying genes and molecules that may be drug target candidates, (see page 21, right column, last paragraph; Figure 1).

Regarding claim 2, Qu et al. shows a data mart that is a multi-dimensional database encompassing information from genes to the biological effects of their expressed proteins, (see page 23 – page 24, middle column).

Regarding claim 3, Qu et al. shows data extracted from multiple public sources such as the Institute for Genome Research, Sanger Center, National Cancer Institute and literature, (see page 24, left column; Figure 1). The specification provides a non-limiting definition of "genomics information" that may comprise information relating to the biological interaction of each of the "concepts" in a pathway, both within the pathway as well as external to the pathway, wherein "concepts" as described in paragraph 42 of the specification, relates to components of a pathway as well as descriptions of how those components relate to the pathway. Qu et al. shows genomics information, i.e. information from genes to the biological effects of their expressed proteins, (see page 23 – page 24, middle column).

Regarding claim 4, Qu et al. shows genomics information obtained from "in house" assays, (see page 22, middle and right columns). Qu et al. shows genomics information, i.e. information from genes to the biological effects of their expressed proteins, (see page 23 – page 24, middle column).

Regarding claims 5, Qu et al. shows genomics information obtained from multiple public sources such as the Institute for Genome Research, Sanger Center, National Cancer Institute and literature, (see page 24, left column; Figure 1) and from "in house" assays, (see page 22, middle and right columns). Qu et al. shows genomics information, i.e. information from genes to the biological effects of their expressed proteins, (see page 23 – page 24, middle column).

Regarding claim 7, the specification defines slots and facets as to define and structure the taxonomic relationship between classes or groups of things that share similar properties, (see specification, page 9, paragraphs 40 and 41). Qu et al. shows ontology vocabulary mapping which provides a formal written description of a specific set of concepts and their relationships in a particular domain based on Stanford University's Gene Ontology Consortium for categorizing molecular function, biological process and cellular components, (see page 22, right column – page 23, left column).

Regarding claim 8, Qu et al. shows functional assays to screen for genes that have important functions in a disease pathway before knowing the genes identities, like cell-cycle functional screening assays and complex protein-protein interactions with several hundred proteins involved in the pathways of interest to elucidate a drug discovery target, (see page 22, middle and right columns; page 25 – page 26; Figure 4).

Regarding claim 9, Qu et al. shows that after specificity and activity of the optimized lead compounds, their drug effects are further characterized in animal models and preclinical studies, (see page 22, left column).

Regarding claim 13, Qu et al. shows incorporating multiple genomes as data sources for the operational relational database, (see page 24, left column; Figure 1).

Regarding claim 14, Qu et al. shows accessing genomics information through data warehousing, (see page 21, right column; page 22, left and middle columns), generating subsets of information that are disease-related pathways through data integration, (see page 22, middle and right columns; pages 25-26, Figure 4) and identifying genes and molecules that may be drug target candidates, (see page 21, right column, last paragraph; Figure 1), such as genes identified from clustering analysis based on YTH and domain data and their biological effects, (see page 25 – page 26, Figures 5 and 6).

Regarding claim 57, Qu et al. shows computer system allowing the accessing of genomics information through data warehousing, (see page 21, right column; page 22, left and middle columns), generating subsets of information that are disease-related pathways through data integration, (see page 22, middle and right columns; pages 25-26, Figure 4) and identifying genes and molecules that may be drug target candidates, (see page 21, right column, last paragraph; Figure 1).

Response to Arguments

Applicant's arguments filed 19 May 2008 have been fully considered but they are not persuasive.

Applicants argue that Qu et al. was published around April 8, 2002 as evidenced by the date stamp provided by the University of Wisconsin Library. Attached. U.S. Patent Application No. 10/632,099. was filed on August 1, 2003 and claims priority to PCT application PCT/US03/03006 filed on February 3, 2003. The PCT application claims priority to U.S. Provisional Application No. 60/353,176 filed on February 4, 2002. Because Qu et al. was published after the filing date of the ' 176 application, it is not prior art to any claim entitled to the priority date. At least claims 1-5, 7, 8, 13, 14, and 57 of the instant application are supported by at least the following disclosures in the provisional application and thereby are entitled to a priority date before Qu et al. was published.

Applicant's arguments are not persuasive.

Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e). A reference to this provisional application is not present in the first paragraph of the specification or in the Application Data Sheet of the instant application. As a result the currently cited art is still applicable to the instant invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-9, 13, 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1- 25 of copending Application No. 10/502420. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application would anticipate the claims of the instant application. The only difference between claim 1 of the instant application and claim 1 of the copending application is that the instant claim 1 comprises “means for accessing genomics information in a database” whereas claim 1 of the copending application comprises “means for storing and accessing genomics information in a database.” Clearly, claim 1 of the copending application teaches accessing genomics information in a database and thus anticipates the instant claim 1. Claims 2-5, 7-9, 13 and 14 of the instant application add similar limitations with only minor differences, to independent claim 1 of the instant application, that claims 22-25 of the copending application add to claim 1 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants argue that upon notification of allowable subject matter, applicants will either timely file a terminal disclaimer or demonstrate that the presently claimed subject matter is patentably distinct from the claimed inventions of the copending applications. Applicants' amendments do not overcome the rejection. Thus, applicant is advised that until claims of the copending and/or the instant application are amended so that the claimed subject matter of the copending and the instant applications is patentably distinct, the rejection under the judicially created doctrine of double patenting will be maintained and no allowable subject matter will be indicated. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

For the reasons stated above and in the previous office action, the rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shubo (Joe) Zhou/
Primary Examiner, Art Unit 1631

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631